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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

DIETARY SUPPLEMENT COALITION, INC. and THE HEALTH HAUS, INC.,

Petitioners,

vs.

DONNA E. SHALALA, Secretary of Health and Human Services, and DAVID A. KESSLER, Commissioner of Food and Drugs,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITIONERS' REPLY BRIEF TO BRIEF IN OPPOSITION

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April 29, 1993

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PETITIONERS' REPLY MEMORANDUM

I. FDA EVADES THE QUESTION PRESENTED FOR REVIEW AND MISREPRESENTS THE LAW ON FOOD ADDITIVES.

In their brief in opposition, respondents (hereafter collectively referred to as "FDA" pursuant to note 1 of

the Petition, at 7) evade the principal question presented for review that has divided the Circuits: Are product seizures final FDA action permitting a separate declaratory judgment action claiming that the product does not violate the FDCA as alleged by the agency? Instead, FDA attempts to re-frame the question as one of administrative review, asserting that it has primary jurisdiction over the classification of substances as food additives, and that petitioners did not exhaust their administrative remedies under such jurisdiction. (Br. in Opp., at I, 10-11). This assertion not only diverts the Court's attention from the

question presented by petitioners,[1] but also misrepresents applicable law.

Neither the FDCA, its legislative history, nor any Federal court decision stands for the proposition that FDA has primary jurisdiction over the food additive status of a substance or product. Rather, it has squarely been held that Federal courts need not defer to FDA on food additive status issues. United States v. 29 Cartons....Oakmont Investment Co., 987 F.2d 33 (1st Cir. 1993).

Nor is FDA's point on exhaustion valid. Companies are free to market substances for use in foods without FDA preclearance, taking the risk that the agency may disagree and attempt to

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[1] For Rule 29.1 statement, see List of Parties at third page of the Petition.

regulate them as unapproved food additives. Southeastern Minerals, Inc. v. Harris, 622 F.2d 758, 760 (5th Cir. 1980); United States v. Articles of Food ... ColiTrol, 518 F.2d 743, 745 (5th Cir. 1975).[2] FDA itself concurs; in its final rule on substances for food use that are generally recognized as safe ("GRAS") and thus not food additives, the agency acknowledged: "persons have the right to make independent GRAS determinations on food substances." 53 Fed. Reg. 16544, 16545 (May 10, 1988).

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[2] The FDCA permits, but does not require, a company to file a food additive petition or a GRAS affirmation petition prior to marketing a substance for use in foods. Id.

II. FDA MISINTERPRETS THE HOLDINGS IN NATICK AND PREMO.

FDA attempts to distinguish the Natick and Premo decisions by characterizing them as cases permitting declaratory claims only "in particular circumstances that included, in addition to the seizures, other agency [administrative] action that strongly indicated that the agency had reached a final decision on the matters at issue." (Br. in Opp., at 7). This contention does not withstand scrutiny. The First and Second Circuits both held that the institution of seizures is final FDA action warranting the exercise of declaratory jurisdiction by district courts, despite related administrative proceedings involving the same products, whether or not such proceedings are final. Natick Paperboard Corp. v. Weinberger, 498

F.2d 125, 128-129 (1st Cir. 1974); Premo Pharmaceutical Laboratories, Inc. v. United States, 629 F.2d 795, 801 (2d Cir. 1980). See also, Petition at 15-16.

III. FDA HAS NOT REGULATED OTHER COQ10 PRODUCTS DIFFERENTLY FROM THE SEIZED PRODUCTS.

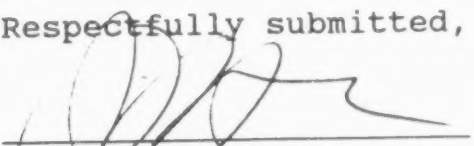
FDA's argument that the CoQ10 seizures were not final agency action because it has not recommended seizure of "all products containing CoQ10" (Br. in Opp., at 8) is meritless. There is no evidence of record demonstrating that FDA regulated or intended to regulate other CoQ10 products any differently from the CoQ10 products that were seized, namely as unapproved food additives.

CONCLUSION

Accordingly, petitioners respectfully urge the Court to grant the petition, and

decide the salient question presented for review that has divided the Circuits.

Respectfully submitted,



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